K132044

510(k) Summary

The following information is provided as required by 21 CFR § 807.87 for the Cranial LOOP, Cranial LOOP L and Cranial LOOP XL Cranial Bone Fixation System 510(k) premarket notification.

Applicant: Neos Surgery S.L.
C/Ceramistes, 2
08290-Cerdanyola del Vallès
Barcelona, Spain

Establishment Registration Number: 3008974316

SEP 3 0 2013

US Contact: Cherita James
M Squared Associates, Inc.
901 King Street, Suite 101
Alexandria, VA 22314
Ph: 703-562-9800 ext 257
Fax: 703-562-9797
E-mail: CJames@msquaredassociates.com

Date submitted: **August 27, 2013**

Proprietary Name: **Cranial LOOP, Cranial LOOP L and Cranial LOOP XL Cranial Bone Fixation System**

Common Name: BurrHole cover

Classification Status: II

Regulation: 21 CFR 882.5250 Burrhole cover

Panel: Neurology

Product Code: GXR

Predicate Device: Cranial LOOP Cranial Bone Fixation System K101235

Device Description: The Cranial LOOP, Cranial LOOP L and Cranial LOOP XL Cranial Bone Fixation System is a biocompatible, postoperative cranial bone fixation system that fixes the bone flap to the skull, without any specific surgical instrument for its handling or implantation. It is provided sterile, for single use. This submission includes a line extension for the Cranial LOOP L

N°	Test	Methodology
A	Functional verification	• Test 1: Functionality of the implantable parts (P01 (lower platform with ties) + P02 (upper platform)): Determine the breaking strength of P01+P02 union (ratchets). A load was applied to the platforms, in an opposite direction, in order to assess the strength of the locking mechanism. • Test 2: Functionality of the handle: Determine the breaking strength of P01 (lower platform with ties) + P03 (handle) union (ratchets). A load was applied to the lower platform and the handle, in an opposite direction, in order to assess the strength of the locking mechanism.
B	Cadaveric test	Three different craniotomies were tested: • Frontal-Parietal-Sphenoid wing craniotomy (left side) • Frontal lateral (right side) • Frontal-parietal (right side). One burr hole on the temporal bone. The craniotomies were obtained using Linvatec cranitome with saws (router) from 1.4 to 2.2 mm cutting diameter and 14 mm diameter perforator.FC050200 (Cranial LOOP XL) are applied in each of the craniotomies according the IFUs. The following aspects were evaluated, 1. Sufficient space for device placement 2. No danger for the surgeon during device application. 3. Correct positioning of the device 4. Rapid and simple application of the device with minimum instruments 5. No danger for duramater. Finally the duramater and the brain will be examined after the removal of the cranial fixation, detecting any possible incidence. 6. Low epicranial and subcranial platform profiles. 7. Adaptation to different cranium curvatures. 8. Adaptation to different cranium thicknesses. 9. Qualitative evaluation of the lateral movement. 10. Qualitative evaluation of cranial fixation strength. 11. Evaluation of the ease with which the system is removed.
C	Biomechanical tests	• Test 1: Strength to bone flap compression (Push-in). A push in load was applied to a model which simulates the cranium and a bone flap with three Cranial LOOPs representing clinical use. • Test 2: Pull-out strength test. A pull out load was applied to a model which simulates the cranium and a bone flap with three Cranial LOOPs representing clinical use. • Test 3: Strength to dynamic load over the bone flap. A push in load to produce a displacement of 0.5 mm on the bone flap, was applied to a model which simulates the cranium and a bone flap with three Cranial LOOPs representing clinical use for 1/2M cycles.
D	Accelerated ageing test	• The following parameters were verified after an aging: a) 'Blister seal strength' (5 samples). b) 'Leak integrity' (5 samples). c) 'Sterility' (5 samples). d) 'Tensile strength' (5 samples) • The accelerated aging was conducted according to the ASTM F 1980 standard. Q10 Factor = 2.0 Real Time aging. RT = 5 years. AAT temperature = 60 °C , AAT = 131,02 days to simulate 5 years of real aging time

and Cranial LOOP XL which have new device dimensions and design features that reduce lateral movement after implantation..

Cranial LOOP and Cranial LOOP L are applied in the craniotomy gap. It can fix cranial thicknesses ranging from 1.5 mm to 24 mm and gaps ranging between 1.7 mm and those made using a craniotome standard cranial router. Cranial LOOP XL is applied in a burr hole made using a standard drill 14 mm. They can fix cranial thicknesses ranging from 4 mm to 24 mm.

Intended Use: The Cranial LOOP Cranial Bone Fixation Systems: Cranial LOOP, Cranial LOOP L and Cranial LOOP XL, are long-term implantable devices indicated for post-craniotomy bone flap fixation.

In cranial bone fixation procedures, the Cranial LOOP (FC050000) and Cranial LOOP L (FC050100) are for use within the calvarial gap while the Cranial LOOP XL (FC050200) is to be used for covering a standard 14 mm cranial burr hole only.

Summary of Technological Characteristics:
The claim of substantial equivalence of the Cranial Loop to the predicate devices is based on the comparison of the intended use, product technical characteristics, performance characteristics and product handling.

Summary of Nonclinical Testing: Mechanical and various performance testing confirms the Cranial LOOP L and Cranial LOOP XL Cranial Bone Fixation System performs as intended and is substantially equivalent to the predicate device. A Declaration of Conformity with design controls is provided.

N°	Test	Methodology
E	Profile and range of bone thickness covered.	Dimensional test are performed in order to validate: • Epicranial and subcranial profile. The epicranial profile protruding from the plane of the bone was measured to ensure it does not exceed the established limits. And the subcranial profile protruding from the plane of the bone was measured to ensure it does not exceed the established limits • Range of bone thickness The upper platform (P02) is lowered as much as possible towards the lower platform (P01). Measure the distance between both platforms in order to check the minimum bone thickness required. The distance between platforms on ready-to-use device is measured in order to check the maximum bone thickness
F	Packaging integrity	• Packaging validation according ISO 11607.

Summary of Clinical Testing: Clinical data was not required in support of this submission.

Substantial Equivalence Discussion:

The line extension for the Cranial LOOP L and Cranial LOOP XL has the following similarities to the previously cleared Cranial LOOP Cranial Bone Fixation System- K101235:

- has the same indicated use,
- uses the same operating principle,
- incorporates the same basic device design,
- incorporates the same materials
- incorporates comparable manufacturing and packaging processes
- incorporates the same sterilization process.

Based on these similarities, and mechanical and performance tests outcomes, the Cranial LOOP L and Cranial LOOP XL are substantially equivalent to the predicate Cranial LOOP Cranial Bone Fixation System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 30, 2013

Neos Surgery S.L.
c/o Cherita James, Regulatory Consultant
M Squared Associates, Inc.
901 King Street, Suite 101
Alexandria, VA 22314

Re: K132044
Trade/Device Name: Cranial LOOP, Cranial LOOP L, Cranial LOOP XL Cranial Fixation System
Regulation Number: 21 CFR 882.5250
Regulation Name: Burr hole cover
Regulatory Class: Class II
Product Code: GXR
Dated: June 21, 2013
Received: July 2, 2013

Dear Ms. James:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: **K132044**

Device Name: Cranial LOOP, Cranial LOOP L, and Cranial LOOP XL Cranial Bone Fixation System

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In cranial bone fixation procedures, the Cranial LOOP (FC050000) and Cranial LOOP L (FC050100) are for use within the calvarial gap while the Cranial LOOP XL (FC050200) is to be used for covering a standard 14 mm cranial burr hole only.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joyce M. Whang -S

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

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